III. REMARKS/ARGUMENTS

A. Status of the Application

Claims 1-24 have been cancelled without prejudice or disclaimer. New claims 25 to 44 have been added. Thus, claims 25 to 44 are currently pending in this application.

New claim 25 is based on cancelled claims 1 and 2. New claim 26 is based on cancelled claim 9. New claim 27 is based on cancelled claim 22. New claims 28-33 are based on cancelled claims 3-8. New claims 34-40 are based on cancelled claims 10-13 and 16-18. New claims 41-42 and 43-44 are based on cancelled claims 23-24 and 20-21, respectively.

No new matter has been added by the amendments and new claims presented herein. Reconsideration of this application in light of the above amendments and the following remarks is respectfully requested.

B. Rejection of Claims 2-13, 16-18 and 20-24 under 37 CFR 1.142(b)

Examiner has withdrawn claims 2-13, 16-18 and 20-24 from consideration as allegedly being directed to a non-elected invention. Claims 2-13, 16-18 and 20-24 have been cancelled without prejudice or disclaimer, and new claims 25-44 have been added, which are directed to a transmembrane delivery system. Contrary to what Examiner has asserted, the originally filed claims are directed to a transmembrane delivery system, rather than to reverse micelles. As the newly presented claims are directed to a transmembrane delivery system, and, therefore, to the same invention as originally claimed and constructively elected, Applicant respectfully submits that they should be permitted to be prosecuted in the present application.

C. Rejection of Claims 3-4, 6-9 and 15-18 under 35 U.S.C. § 112

Claims 3-4, 6-9 and 15-18 have been rejected under 35 U.S.C. § 112, second paragraph. This rejection has been rendered moot by the cancellation of these claims. In addition, the objections raised against the cancelled claims have been addressed by the newly presented claims as detailed in the comments set forth below.

New claims 28 and 29, which are based on cancelled claims 3 and 4, make use of the term the term "reverse micelles" instead of the term "micelles", and do not make reference to "in a fluid environment".

New claim 31, which is based on cancelled claim 6 makes reference to the "amphipathic ionic compound" of new claim 25.

New claim 32, which is based on cancelled claim 7 does not make reference to "high solubility" and "low permeability". Applicant submits that recitation of a "Class III biopharmaceutical" in new claim 32 is not indefinite because those of ordinary skill in the art would recognize and understand what is meant by the recitation. (*See e.g.,* Amidon, GL *et al.*, *"A theoretical basis for a biopharmaceutic drug classification: the correlation of in vitro drug product dissolution and in vivo bioavailability"*, Pharm Res. (3):413-20, 1995). A copy of the Amidon abstract is provided as Attachment A.

New claim 33 is based on cancelled claim 8. With respect to the rejection under 35 U.S.C. § 112, second paragraph, Applicant notes that new claim 25, from which new claim 33 depends, sets forth a composition comprising an amphipathic ionic compound in monomeric form, and a polar ionizable agent of interest. Applicant submits that the antecedent basis established in new claim 25 is sufficiently clear for the recitations in new claim 33.

New claim 26, which is based on cancelled claim 9, makes use of the term "amphipathic ionic compound" instead of "amphipathic compound".

New claim 42 is based on cancelled claim 15, and does not include the terms "urinary" and "vaginal".

New claim 38 is based on cancelled claim 16 and makes use of the term "matrix" instead of the term "matrix-type".

New claims 39-40 are based on cancelled claims 17-18. Applicant notes that new claim 25, from which new claims 39 and 40 depend, sets forth a composition comprising an amphipathic ionic compound in monomeric form, and a polar ionizable agent of interest. Applicant submits that the subject matter of new claim 25 is such that it can be manipulated in a solid state as recited in new claims 39 and 40.

In view of the foregoing, Applicant respectfully requests that the rejection of claims 3-4, 6-9, and 15-18 under 35 U.S.C. § 112, second paragraph be withdrawn.

D. Rejection of Claim 19 under 35 U.S.C. § 101

Claim 19 stands rejected under 35 U.S.C. § 101. This rejection has been rendered moot by the cancellation of claim 19.

E. Rejection of Claims 1-9, 13-15 and 18-21 under 35 U.S.C. 102(b)

Claims 1-9, 13-15 and 18-21 stand rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,292,499 to Evans et al. (hereafter referred to as "Evans"). This rejection is respectfully traversed.

As provided in MPEP § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim...." Therefore, Evans must disclose all of the elements of the claims to sustain the rejection under 35 U.S.C. §102(b). Claims 1-9, 13-15 and 18-21 have been cancelled. As applied to the newly presented claims, Applicant notes that Evans does not meet the standard required by MPEP § 2131 because Evans does not disclose or suggest each and every element of independent claim 25 or the claims dependent thereon.

New claim 25 is drawn to a delivery system comprising one or more than one amphipathic ionic compound in monomeric form, and one or more than one polar ionizable agent of interest. After the delivery system is contacted with an aqueous fluid, a reverse micelle comprising the amphipathic ionic compound and the polar ionizable agent of interest is formed. As disclosed at page 13, line 17 to page 14, line 11 of the present application, when the delivery system comes into contact with an external fluid, a release of the amipathic ionic compound and the agent of interest occurs. The released amphiphilic ionic compound and agent of interest attract each other and form reverse micelles containing the agent of interest and the amphiphilic compound. The reverse micelles can then partition into, for example a lipophilic membrane, and undergo disaggregation and release of the agent of interest.

In contrast, Evans discloses an aerosol formulation comprising water, a propellant, and reverse micelles of a hydrophilic pharmaceutically active agent. The aerosol formulation, which includes water and the reverse micelles, is delivered to a patient. (See e.g., Col. 6, lines 44-54.) While Evans discloses a reverse micelle, which is known by those of ordinary skill in the art to be a polymeric or aggregate molecule, Evans does not disclose or suggest a delivery system comprising an amphipathic ionic compound in monomeric form and a polar ionizable agent of interest. Moreover, Evans does not disclose or suggest a delivery system wherein a reverse micelle comprising an amphipathic ionic compound and a polar ionizable agent of interest is formed after the delivery system is contacted with an aqueous fluid.

New claims 26-44 each depend directly or indirectly from new claim 25. Thus, new claims 26-44 are also novel in view of Evans for at least the same reasons as applied to new claim 25

In view of the foregoing, Applicants request that the rejection of claims 1-9, 13-15 and 18-21 under 35 U.S.C. § 102(b) over Evans be withdrawn.

F. Rejection of Claims 1-6, 8-11, 13-15 and 18 under 35 U.S.C. § 102(b)

Claims 1-6, 8-11, 13-15 and 18 stand rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,770,172 to Linehan et al. (hereafter referred to as "Linehan"). This rejection is respectfully traversed.

As provided in MPEP § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim...." Therefore, Linehan must disclose all of the elements of the claims to sustain the rejection under 35 U.S.C. §102(b). Claims 1-6, 8-11, 13-15 and 18 have been cancelled. As applied to the newly presented claims, Applicant notes that Linehan does not meet the standard required by MPEP § 2131 because Linehan does not disclose or suggest each and every element of new independent claim 25 or the claims dependent thereon.

New claim 25 is drawn to a delivery system comprising one or more than one amphipathic ionic compound in monomeric form, and one or more than one polar ionizable agent of interest. After the delivery system is contacted with an aqueous fluid, a reverse micelle comprising the amphipathic ionic compound and the polar ionizable agent of interest is formed. As disclosed at page 13, line 17 to page 14, line 11 of the present application, when the delivery system comes into contact with an external fluid, a release of the amipathic ionic compound and the agent of interest occurs. The released amphiphilic ionic compound and agent of interest attract each other and form reverse micelles containing the agent of interest and the amphiphilic compound. The reverse micelles can then partition into, for example a lipophilic membrane, and undergo disaggregation and release of the agent of interest.

In contrast, Linehan describes a process for producing a nanometer-sized metal compound. According to the process described in Linehan, a water-soluble metal compound is reacted in a reverse micelle to form a nanometer-sized metal compound. The nanometer-sized compound is precipitated from the reverse micelle. (Col. 5, lines 32-37). Linehan does not disclose or suggest a delivery system comprising an amphipathic ionic compound in monomeric form and a polar ionizable agent of interest. Further, Linehan does not disclose or suggest a

delivery system wherein a reverse micelle comprising an amphipathic ionic compound and a polar ionizable agent of interest is formed after the delivery system is contacted with an aqueous fluid.

New claims 26-44 each depend directly or indirectly from new claim 25. Thus, new claims 26-44 are also novel in view of Linehan for at least the same reasons as applied to new claim 25.

In view of the foregoing, Applicants request that the rejection of claims 1-6, 8-11, 13-15 and 18 under 35 U.S.C. § 102(b) over Linehan be withdrawn.

G. Rejection of Claims 1-2, 5-7, 12-14 and 16-21 under 35 U.S.C. § 102(a)

Claims 1-2, 5-7, 12-14 and 16-21 stand rejected under 35 U.S.C. § 102(a) over U.S. Patent No. 6,316,497 to Liu et al. (hereafter referred to as "Liu"). This rejection is respectfully traversed.

As provided in MPEP § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim...." Therefore, Liu must disclose all of the elements of the claims to sustain the rejection under 35 U.S.C. §102(a). Claims 1-2, 5-7, 12-14 and 16-21 have been cancelled. As applied to the newly presented claims, Applicant notes that Liu does not meet the standard required by MPEP § 2131 because Liu does not disclose or suggest each and every element of new independent claim 25 or the claims dependent thereon.

New claim 25 is drawn to a delivery system comprising one or more than one amphipathic ionic compound in monomeric form, and one or more than one polar ionizable agent of interest. After the delivery system is contacted with an aqueous fluid, a reverse micelle comprising the amphipathic ionic compound and the polar ionizable agent of interest is formed. As disclosed at page 13, line 17 to page 14, line 11 of the present application, when the delivery system comes into contact with an external fluid, a release of the amipathic ionic compound and the agent of interest occurs. The released amphiphilic ionic compound and agent of interest attract each other and form reverse micelles containing the agent of interest and the amphiphilic compound. The reverse micelles can then partition into, for example a lipophilic membrane, and undergo disaggregation and release of the agent of interest.

In contrast, Liu discloses a system comprising o-(chloroacetylcarbamoyl)fumigillol, a pharmaceutically acceptable carrier, and a stabilizing component, such as water, acid or a complex-forming agent. When water is the stabilizing component in the system, and surfactants

are present, reverse micelles form. The formation of the reverse micelles protects the o-(chloro acetylcarbamoyl)fumigillol from degradation, or stabilizes the o-(chloroacetylcarbamoyl) fumigillol in the macroscopically homogeneous SES solution. (Col. 5, lines 24-37). Thus, Liu describes forming a system in which reverse micelles are formed prior to administration of a drug so that the drug remains intact for administration.

While Liu discloses a reverse micelle, which is known by those of ordinary skill in the art to be a polymeric or aggregate molecule, Liu does not disclose or suggest a delivery system comprising an amphipathic ionic compound in monomeric form and a polar ionizable agent of interest. Moreover, Liu does not disclose or suggest a delivery system wherein a reverse micelle comprising an amphipathic ionic compound and an polar ionizable agent of interest is formed after the delivery system is contacted with an aqueous fluid.

New claims 26-44 each depend directly or indirectly from new claim 25. Thus, new claims 26-44 are also novel in view of Liu for at least the same reasons as applied to new claim 25.

In view of the foregoing, Applicants request that the rejection of claims 1-2, 5-7, 12-14 and 16-21 under 35 U.S.C. § 102(a) over Liu be withdrawn.

H. Rejection of Claims 1, 5-7, 9-10, 13-15 and 19-21 under 35 U.S.C. § 102(e)

Claims 1, 5-7, 9-10, 13-15 and 19-21 stand rejected under 35 U.S.C. § 102(e) over U.S. Patent No. 6,429,200 to Monahan et al. (hereafter referred to as "Monahan"). This rejection is respectfully traversed.

As provided in MPEP § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim...." Therefore, Monahan must disclose all of the elements of the claims to sustain the rejection under 35 U.S.C. §102(e). Claims 1, 5-7, 9-10, 13-15 and 19-21 have been cancelled. As applied to the newly presented claims, Applicant notes that Monahan does not meet the standard required by MPEP § 2131 because Monahan does not disclose or suggest each and every element of new independent claim 25 or the claims dependent thereon.

New claim 25 is drawn to a delivery system comprising one or more than one amphipathic ionic compound in monomeric form, and one or more than one polar ionizable agent of interest. After the delivery system is contacted with an aqueous fluid, a reverse micelle comprising the amphipathic ionic compound and the polar ionizable agent of interest is formed. As disclosed at page 13, line 17 to page 14, line 11 of the present application, when the delivery

system comes into contact with an external fluid, a release of the amipathic ionic compound and the agent of interest occurs. The released amphiphilic ionic compound and agent of interest attract each other and form reverse micelles containing the agent of interest and the amphiphilic compound. The reverse micelles can then partition into, for example a lipophilic membrane, and undergo disaggregation and release of the agent of interest.

In contrast, Monahan discloses a complex for administration to a patient, which is formed by inserting a nucleic acid into a reverse micelle. (Abstract). Thus, Monahan describes a complex in which reverse micelles are formed prior to administration of a drug. While Monahan discloses a reverse micelle, which is known by those of ordinary skill in the art to be a polymeric or aggregate molecule, Monahan does not disclose or suggest a delivery system comprising an amphipathic ionic compound in monomeric form and a polar ionizable agent of interest. Moreover, Monahan does not disclose or suggest a delivery system wherein a reverse micelle comprising an amphipathic ionic compound and an polar ionizable agent of interest is formed after the delivery system is contacted with an aqueous fluid.

New claims 26-44 each depend directly or indirectly from new claim 25. Thus, new claims 26-44 are also novel in view of Monahan for at least the same reasons as applied to new claim 25.

In view of the foregoing, Applicants request that the rejection of claims 1, 5-7, 9-10, 13-15 and 19-21 under 35 U.S.C. § 102(a) over Monahan be withdrawn.

IV. CONCLUSION

Claims 25-44 are under consideration in the present application. In view of the foregoing remarks, allowance of claims 25-44 is respectfully requested.

PATENT / DOCKET NO.: 25000.9
CUSTOMER NO.: 27683

The examiner is invited to call the undersigned at the below-listed telephone number if in the opinion of the examiner such a telephone conference would expedite or aid the prosecution and examination of this application.

Respectfully submitted,

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Dated: March 15, 2005

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